

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Thomas Vanaskie
(Ret.),
Special Discovery Master

**DECLARATION OF KELLY A. BONNER
PURSUANT TO LOCAL RULE 5.3(g)**

I, Kelly A. Bonner, of full age, hereby declare as follows:

1. I am an attorney at law of the State of New York and the Commonwealth of Pennsylvania, a member of good standing of the bars of the United States Courts of Appeals for the Second and Ninth Circuits, the United States District Court for the Eastern District of Pennsylvania, and this Court pending *pro hac vice* admission, and am employed with the law firm of Duane Morris LLP, counsel to Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Princeton Pharmaceutical Inc. (“Princeton”), Huahai U.S. Inc. (“Huahai U.S.”), and Solco Healthcare U.S. LLC (“Solco”, and collectively with ZHP, Huahai U.S., and Princeton, “the ZHP Parties”).

2. I make this Declaration on behalf of the ZHP Parties in support of their Motion to Seal Pursuant to Local Rule 5.3(c).

3. On July 23, 2021, Plaintiffs filed the Motion to Compel (ECF. No. [1405](#)), which attached as exhibits seventeen documents designated by the ZHP Parties as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” under the Protective Order. Plaintiffs subsequently challenged the ZHP Parties’ confidentiality designations as to these seventeen exhibits.

4. The parties agreed to extend the deadline for the ZHP Parties to resolve Plaintiffs’ challenges or otherwise file a motion to seal the exhibits is October 12, 2021. *See* Letter from Seth Goldberg dated September 28, 2021 at 12 (ECF. No. [1587](#)) (“The Parties have reached an agreement stipulating that the deadline for the ZHP Parties to resolve these challenges or move to seal such documents is October 12, 2021.”)

5. Following careful review of the seventeen challenged exhibits, the ZHP Parties have affirmatively agreed to de-designate seven exhibits as not confidential (Exhibits 11-13, 17-19, 28).⁴

⁴ The ZHP Parties have requested, and Plaintiffs consented to, a redaction of an account number contained in Exhibit 17 pursuant to Fed. R. Civ. P. 5.2(a)

6. However, the ZHP Parties cannot agree to de-designate the remaining ten documents because they (1) implicate third party privacy interests protected by confidentiality agreements; or (2) disclose proprietary, non-public product testing information that would be of significant competitive value to the ZHP Parties' competitors.

7. Because these ten exhibits to the Motion to Compel were designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" pursuant to Paragraphs 9 (B) and (M) of the Protective Order, the ZHP Parties formally move to seal the following exhibits pursuant to Paragraph 31 of the Protective Order, as well as Local Civil Rule 5.3(c):

- a. **ZHP02471924** (ECF No. [1405](#), Ex. 4) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A letter from one of the ZHP Parties' customers, Novartis International Pharmaceuticals Ltd., Branch Ireland ("NIPBI"), to ZHP employees dated July 19, 2018, regarding the return of valsartan API delivered to NIPBI, which is subject to a mutual confidential disclosure agreement between NIPBI and the ZHP Parties. *See* Index at 1 (citing Xu Decl. ¶¶ 3-5).
- b. **ZHP02734637** (ECF No. [1405](#), Ex. 5) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): A duplicate of ZHP02471924 (ECF No. [1405](#), Ex. 4), described in the paragraph above. *See id.*

- c. **ZHP02490581** (ECF No. [1405](#), Ex. 6) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): A letter from Sandoz AG and Sandoz Pvt. Ltd. to ZHP employees dated January 15, 2019 regarding a notification of claims and actions involving the affiliates of Sandoz Pvt. Ltd. and Sandoz AG (collectively, “Sandoz”) related to the ZHP Parties’ product, which was not intended for the U.S. market, and is subject to a confidentiality provision in the API supply agreement between Sandoz and the ZHP Parties. *See* Index at 2 (citing Xu Decl. ¶¶ 7-9).
- d. **ZHP02735368** (ECF No. [1405](#), Ex. 7) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): A duplicate of ZHP02490581 (ECF No. [1405](#), Ex. 6), described in the paragraph above. *See id.*
- e. **ZHP02731217** (ECF No. [1405](#), Ex. 8) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): Non-public, internal communications between ZHP employees dated January 13, 2018 regarding testing of the ZHP Parties’ irbesartan intermediate compounds, which describes non-public, proprietary testing practices and procedures unrelated to the claims at issue in this litigation. *See* Index at 3 (citing Li Decl. ¶ 3).

- f. **ZHP00180427** (ECF No. [1405](#), Ex. 9) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): Emails dated April 28 through May 3, 2017 between employees from the ZHP Parties and those of the ZHP Parties’ customer, MacLeods Pharmacy, regarding chromatography testing of the ZHP Parties’ valsartan KSM, which were subject to a mutual confidential disclosure agreement between the ZHP Parties and MacLeods Pharmacy, and continuing confidentiality obligations pursuant to the relevant purchase order terms and conditions. *See* Index at 4 (citing Xu Decl. ¶¶ 11-14).
- g. **ZHP02628144** (ECF No. [1405](#), Ex. 10) (designated “CONFIDENTIAL INFORMATION”): Non-public communications between the ZHP Parties and a potential business partner from November-December 2017 regarding a draft valsartan synthesis process development contract, in which the ZHP Parties and their intended business partner discuss proposed revisions to the draft agreement prior to its implementation, including whether the agreement should include four pharmaceutical products not related to valsartan, and whether their intended business partner has the technical capability to include the additional products subject to the ZHP Parties’

specifications, as well as considerations for future collaborations and material cost calculations. *See* Index at 5 (citing Xu Decl. ¶¶ 16-17).

- h. **ZHP02710347** (ECF No. [1405](#), Ex. 14) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): An investigation report prepared by the ZHP Parties, which details proprietary specifications and testing methods for impurities related to irbesartan and unrelated to the claims at issue in this litigation. *See* Index at 6 (citing Li Decl. ¶ 4).
- i. **ZHP02710344** (ECF No. 1405, Ex. 15) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): Internal, non-public pilot test results from May 2, 2017 to August 10, 2017 that detail the ZHP Parties’ proprietary specifications and testing methods for impurities in irbesartan. *See* Index at 7 (citing Li Decl. ¶ 5).
- j. **ZHP02710242** (ECF No. [1405](#), Ex. 16) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): Internal, non-public experiment results regarding the testing and validation of irbesartan samples from August 21, 2017 to December 29, 2017 that detail the ZHP Parties’ proprietary specifications and testing methods for impurities in irbesartan. *See* Index at 10 (citing Li Decl. ¶ 6).

8. Likewise, Plaintiffs have redacted a portion of a sentence of their Motion to Compel disclosing confidential information contained in Exhibits 14-16.

See Mot. to Compel at 9 (ECF No. [1405](#)). Because the ZHP Parties seek to seal Exhibits 14-16 in their entirety, for the same reasons described herein, the ZHP Parties seek to maintain that redaction in the Motion to Compel.

9. In support of the Motion to Seal and in accordance with Local Civil Rule 5.3(c)(3), the ZHP Parties have prepared and have submitted the following declarations:

- a. A true and correct copy of the Declaration of Mi Xu, with personal knowledge of Exhibits 4, 5, 6, 7, 9, and 10, and attesting to the confidential nature of those documents, is attached to this Declaration as **Exhibit A**.
 - b. A true and correct copy of the Declaration of Dr. Min Li, with personal knowledge of Exhibits 8, 14, 15, and 16, and attesting to the confidential nature of those documents, is attached to this Declaration as **Exhibit B**.
10. Together, these Declarations describe with particularity: (a) the nature of the exhibits to be sealed; (b) the legitimate interest that warrants the relief sought; (c) the clearly defined and serious injury that would result to the ZHP Parties if the relief sought is not granted.
11. A true and correct copy of the index required by Local Rule 5.3(c)(3) is attached hereto as **Exhibit C**.

12. There is no less restrictive alternative to moving to seal the exhibits. The ZHP Parties carefully analyzed all seventeen of the challenged exhibits to identify which information should be sealed, have agreed to de-designate seven (7) out of seventeen total challenged exhibits, and seek to seal only those exhibits that cannot be de-designated because they implicated third party privacy interests or otherwise contain commercially sensitive or proprietary, non-public information regarding the ZHP Parties' testing procedures that was appropriately designated as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" by the ZHP Parties pursuant to the Protective Order.

13. There is no prior Order sealing the exhibits, or the confidential information discussed therein.

14. Plaintiffs have objected to the ZHP Parties' sealing request on several grounds.

15. First, Plaintiffs have objected to the ZHP Parties' request to seal Exhibits 4, 5, 6, and 7 on the grounds that confidential treatment is not justified under the Protective Order in light of their belief that the ZHP Parties have waived confidentiality as to Exhibits 4 and 6 (of which Exhibits 5 and 7 are duplicates), and that they appear to discuss matters of public knowledge.

16. The ZHP Parties dispute Plaintiffs' allegation that they waived confidentiality as to Exhibits 4 and 6 (let alone Exhibits 5 and 7), and this issue has

been fully briefed and is *sub judice*. The ZHP Parties maintain the appropriateness of their confidentiality designation of these exhibits as “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to Paragraph 9(M) of the Protective Order.

17. Nor have Plaintiffs asserted any basis for their assertion that these communications contain matters of public knowledge where the contents of these communications are not publicly known, but rather, as described in the Xu Declaration, represent confidential information exchanged pursuant to confidentiality agreements.

18. Second, Plaintiffs have objected to the ZHP Parties’ request to seal Exhibit 10 on the grounds that confidential treatment is not justified under the Protective Order because Plaintiffs allege that Exhibit 10 is a routine business communication that does not warrant sealing as a court record.

19. But as described in the Xu Declaration, Exhibit 10 contains non-public communications between the ZHP Parties and a potential business partner regarding proposed revisions to a draft valsartan synthesis process development contract, including whether to expand the agreement’s provisions to encompass products unrelated to valsartan, as well as material costs and product specifications. *See Xu Decl.* at ¶¶ 16-17.

20. Third, Plaintiffs have objected to the ZHP Parties' request to seal Exhibits 8, 9, 14, 15, and 16 on the grounds that confidential treatment is not justified under the Protective Order in light of what they argue is the public's right to access them as court records. But Plaintiffs have not delineated how any of the information contained in Exhibits 8, 9, 14, 15, and 16 would have any impact on public knowledge of health or safety issues, let alone advance any current or immediate public health interest, or possess any current value to the general public that would outweigh the ZHP Parties interest in preserving the confidentiality of their proprietary product testing methods with the goal of improving and optimizing the ZHP Parties' manufacturing processes.

I, Kelly A. Bonner, declare under penalty of perjury that the foregoing is true and correct.

Executed on October 12, 2021.

/s/ Kelly A. Bonner
Kelly A. Bonner